AMENDMENTS 001-105
by the Committee on the Environment, Public Health and Food Safety

Report
Miroslav Mikolášik **A7-0106/2010**
Standards of quality and safety of human organs intended for transplantation

Proposal for a directive (COM(2008)0818 – C6-0480/2008 – 2008/0238(COD))

Amendment 1

Proposal for a directive
Recital 1

Text proposed by the Commission	*Amendment*
(1) Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs for transplantation has steadily increased during the last two decades. Organ transplantation is now the ***most cost-effective*** treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment.	(1) Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs for transplantation has steadily increased during the last two decades. Organ transplantation is now the treatment ***with the best risk/benefit ratio*** for end-stage renal ***and pancreatic*** failure, while for end-stage failure of organs such as the liver, lung***, intestines*** and heart it is the only available treatment.

Justification

If the organ transplantations which are feasible according to the state of the art are to be listed, it is important to ensure that the list is as exhaustive as possible.

Amendment 2

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases.	(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases. ***Well-organised national transplant systems and use of the best available expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs for patients.***

Justification

Immunological problems after transplantation are not the best example of the potential benefits of the Directive

Amendment 3

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of ***expanding the pool of organs available and*** ensuring a better match between donor and recipient and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.	(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of ensuring a better match between donor and recipient and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

Justification

Matching donors and recipients is the prime reason for setting up European organ exchange

organisations such as Scandinavtransplant or Eurotransplant. This model of pan-European exchanges, effective though it may be, does not have the aim of expanding the pool of available organs. In order to do so, new strategies need to be adopted both nationally and at Community level.

Amendment 4

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) There is therefore a need for common quality and safety standards for the procurement, transport and use of human organs at Community level. These standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Community legislation should ensure that human organs comply with ***acceptable*** standards of quality and safety. Therefore such standards will help to reassure the public that human organs procured in another Member State nonetheless carry the same basic quality and safety guarantees as those obtained in their own country.	(6) There is therefore a need***, while duly respecting the subsidiarity principle pursuant to Article 168(7) TFEU,*** for common quality and safety standards for the procurement, transport and use of human organs at Community level. These standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Community legislation should ensure that human organs comply with ***recognised*** standards of quality and safety. Therefore such standards will help to reassure the public that human organs procured in another Member State nonetheless carry the same basic quality and safety guarantees as those obtained in their own country.

Justification

Art. 168 Abs. 7 AEUV bestimmt, dass bei der Tätigkeit der Union die Verantwortung der Mitgliedstaaten für die Festlegung ihrer Gesundheitspolitik sowie für die Organisation des Gesundheitswesend und die medizinische Versorgung gewahrt wird. Maßnahmen zur Festlegung hoher Qualitäts- und Sicherheitsstandards für Organe lassen einzelstaatliche Regelungen über die Spende oder die medizinische Verwendung von Organen unberührt. Da sich die Begriffe Beschaffung und Spende teilweise überschneiden, ist der Hinweis auf das Subsidiaritätsprinzip unbedingt erforderlich. Nur anerkannte Qualitäts- und Sicherheitsstandards spiegeln den Stand der medizinischen Wissenschaft wider.

Amendment 5

Proposal for a directive
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) In accordance with Article 168(7) TFEU, the measures adopted under paragraph 4(a) of that Article do not affect national provisions on the medical use of organs. Therefore the surgical act of transplantation itself does not fall within the scope of this Directive. However, in view of the objective of reducing the associated risks of the transplanted organs, it is necessary to include in this Directive certain provisions concerning the transplantation process and in particular provisions aimed at addressing those unintended and unexpected situations occurring during the transplantation that might affect the quality and safety of organs.

Amendment 6

Proposal for a directive
Recital 7

Text proposed by the Commission	*Amendment*
(7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme. This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations.	(7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme***, ensuring that they have a precise description of the donor and the organs***. This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations.

Justification

Self-explanatory.

Amendment 7

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(10) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. This evaluation must provide enough information for the transplant centre to undertake a proper risk-benefit analysis. The risks and characteristics of the organ must be identified and documented to allow allocation to a suitable recipient. Information should be collected for complete characterisation of the organ and the donor.	(10) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. This evaluation must provide enough information for the transplant centre to undertake a proper risk-benefit analysis. The risks and characteristics of the organ must be identified and documented to allow allocation to a suitable recipient. Information ***from clinical history, physical examination and complementary tests*** should be collected for complete characterisation of the organ and the donor. ***In order to obtain an accurate, reliable and objective medical history, the medical team should interview the living donor or the relatives of the deceased donor. This is essential since the time constraints of the process of deceased donation reduce the ability to rule out potentially serious transmissible diseases. During the interviews, the team should properly inform the interviewees of the risks and consequences of donation and transplantation so as to make them aware of the importance of providing the medical team with all relevant information.***

Justification

The importance of obtaining an appropriate medical history should be stressed as an essential point for ensuring the quality and safety of organs for transplantation. For that purpose the concept of properly informing donors/relatives to make them understand the potential risks for the recipient should be included.

Amendment 8

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(14) Personnel directly involved in the donation, ***procurement,*** testing, preservation, transport and transplantation of human organs should be ***suitable*** qualified and ***trained.***	(14) Personnel directly involved in the donation, testing, ***characterisation, procurement,*** preservation, transport and transplantation of human organs should be ***suitably*** qualified and ***competent.***

Justification

It should be clarified that these requirements apply only to healthcare personnel involved in the process. Asking for such strict requirements for other personnel might lead to a necessary loss of organs. The steps are suggested to be ordered according to clinical practice and to be consistent with article 2 of the Directive. The new wording better captures the EU MS realities and clarifies that it is not intended to increase the administrative burden

Amendment 9

Proposal for a directive
Recital 16

Text proposed by the Commission	*Amendment*
(16) This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In line with that charter and to take account of, as appropriate the Convention on human rights and biomedicine , organ transplantation programmes should be founded on the principles of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring ***anonymity of the deceased donor and the recipient(s).***	(16) ***In order to ensure the quality and safety of organs for transplantation, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation. This is an essential aspect, since the violation of these principles might be associated with unacceptable risks and poor outcomes for recipients and living donors. When donation is not voluntary or provides for financial gain, the quality of the process of donation cannot be fully guaranteed, since improving the quality of life or saving the life of a person is not the main or sole objective to be achieved. Even if the process is developed in accordance with appropriate quality standards, the clinical history obtained either from the***

potential living donor or the relatives of the potential deceased donor might not be accurate enough in terms of those conditions or diseases which are potentially transmissible from donors to recipients when donors are seeking financial gain or are subjected to any kind of coercion. This would result in a safety problem for potential recipients since the team would have a limited capability for performing an appropriate risk analysis.

This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union . In line with that charter and to take account of, as appropriate the Convention on human rights and biomedicine , organ transplantation programmes should be founded on the principles of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring ***that strict confidentiality rules and security measures are in place for the protection of the donors' and the recipients' personal data.***

Justification

The concepts of 'traceability' and 'identifiability' are strongly connected to each other: whenever traceability of the holders of the biological materials is possible, either in a direct or indirect way, these holders can be considered as identifiable. From a data protection perspective, traceability and anonymity of data cannot appear at the same time since they are opposite to each other. However, the proposal still uses both terms and therefore creates a contradiction .Recital 16 should be more focused on reinforcing the relation between Chapter III (principles governing organ donation) and quality and safety of organs intended for transplantation.

Amendment 10

Proposal for a directive
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) The competent authority should consult with the national Data Protection Authority in relation to developing a

framework for the transfer to and from third countries of data concerning organs. The specific regime for the transfer of personal data to third countries as laid down in Articles 25 and 26 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[1] should apply.

[1] OJ L 281, 23.11.1995, p. 31.

Justification

A specific regime for transfer of personal data to third countries is laid down in Articles 25 and 26 of Directive 95/46/EC. Article 21 or the relevant Recital 15 of the proposal could state that the competent authority will consult with the national Data Protection Authority in order to develop the necessary framework for secure, but also fast and efficient transfer of organs' data to and from the third countries.

Amendment 11

Proposal for a directive
Recital 16 b (new)

Text proposed by the Commission	*Amendment*
	(16b) As a general principle, the identity of the recipient(s) should not be disclosed to the donor or the donor's family or vice versa, without prejudice to legislation in force in Member States which, under specific conditions, might allow such information to be made available to donor or donors' families and organ recipients with the consent of both parties.

Justification

The maintenance of anonymity between donor and recipient initially placed in recital 16 of the original proposal is better to be explained in a new specific recital. This would clarify that this principle of anonymity is not referred to a procedure to ensure data protection, since this last one would be in contradiction with the traceability.

Amendment 12

Proposal for a directive
Recital 16 c (new)

Text proposed by the Commission	*Amendment*
	(16c) Combating organ trafficking should not remain the responsibility of the Union alone. Member States should also take measures to that end, including reducing demand, promoting organ donation more effectively, maintaining strict legislation with regard to live donors, guaranteeing transparency of national registers and waiting lists, establishing the legal responsibility of the medical profession for tracking irregularities, and sharing information.

Amendment 13

Proposal for a directive
Recital 17

Text proposed by the Commission	*Amendment*
(17) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[13] prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition ***principle*** are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing.	(17) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[13] prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing. ***In line with that Directive, strict confidentiality rules and security measures should be in place for the protection of donors' and recipients' personal data. Moreover, the competent authority may also consult the national Data Protection Authority in relation to developing a framework for the transfer to and from third countries of***

data concerning organs.

Justification

Confidentiality rules and security measures should be taken for the protection of the donors' and recipients' personal data. We make the reference under this recital which establishes clearly the obligation to comply with the requirements stated in Directive 95/46/EC.

Amendment 14

Proposal for a directive
Recital 19

Text proposed by the Commission	*Amendment*
(19) The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation. As emphasised by the Recommendation of the Committee of Ministers to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO) of the Council of Europe , it is preferable to have a single body which is officially recognised and non-profit making with overall responsibility for donation, allocation, traceability and accountability. However, depending especially on the repartition of competences within the Member States, a combination of local, regional, national and/or international bodies may work together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency	(19) The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation ***and throughout the patient's recovery, based on best medical practice in post-transplantation treatment***. As emphasised by the Recommendation of the Committee of Ministers to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO) of the Council of Europe15, it is preferable to have a single body which is officially recognised and non-profit making with overall responsibility for donation, allocation, traceability and accountability. However, depending especially on the repartition of competences within the Member States, a combination of local, regional, national and/or international bodies may work together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency

Justification

The transplant process does not end when the patient has received an organ in the transplant operation. The recovery period, and treatment with anti-rejection therapies, are also imperative to the success, or not, of a transplanted organ for the patient. This fact should not be neglected

as it is a vital part of whether the patient has undergone a successful transplant and is ultimately able to improve their health.

Amendment 15

Proposal for a directive
Recital 21

Text proposed by the Commission	*Amendment*
(21) The measures needed to implement this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.	(21) The measures needed to implement this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission. ***With regard to Article 25, in all cases of implementing measures affecting data protection and security, all relevant stakeholders should be consulted, including the European Data Protection Supervisor.***

Justification

The legislator should ensure that, with regard to Article 25, in all cases where implementing measures affecting data protection and security are considered, all relevant stakeholders are consulted, including the EDPS.

Amendment 16

Proposal for a directive
Recital 22

Text proposed by the Commission	*Amendment*
(22) ***In particular, power should be conferred on the Commission to lay down,*** where the organs concerned are to be exchanged between Member States, the procedures for the transmission to transplantation centres of the information on the characteristics of the organs, the procedures needed to ensure the traceability of the organs, including labelling requirements, and the procedures for the reporting of serious adverse events or reactions. ***Since these measures are of general scope and are designed to amend***	(22) ***In order to achieve the objectives of this Directive, the Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU concerning,*** where the organs concerned are to be exchanged between Member States, the procedures for the transmission to transplantation centres of the information on the characteristics of ***the donor and*** the organs, the procedures needed to ensure the traceability of the organs, including labelling requirements, and the procedures for the reporting of

non-essential elements of this Directive, or to supplement this Directive with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.	serious adverse events or reactions.

Justification

The legislator should ensure that, with regard to Article 25, in all cases where implementing measures affecting data protection and security are considered, all relevant stakeholders are consulted, including the EDPS.

Amendment 17

Proposal for a directive
Article 2 - paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. This Directive shall not prevent Member States from maintaining or introducing more stringent protective measures, provided that they comply with the provisions of the Treaty.

Amendment 18

Proposal for a directive
Article 3 – point a

Text proposed by the Commission	*Amendment*
(a) 'authorisation' means ***authorisation***, accreditation, ***designation or*** licensing, depending ***of*** the ***concepts*** used in each Member State;	(a) 'authorisation' means accreditation, ***authorisation,*** licensing ***or certification***, depending ***on*** the ***regulatory approaches*** used in each Member State;

Justification

The new wording is based on the concepts in the Tissues Directive 2004/23/EC and covers the various national regulatory approaches.

Amendment 19

Proposal for a directive
Article 3 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) 'competent authority' means a non-profit authority, body, organisation or institution, whether public or private, that is responsible for implementing the provisions of this Directive.

Amendment 20

Proposal for a directive
Article 3 – point c

Text proposed by the Commission	*Amendment*
(c) ***'***donor' means ***every human source of*** organs, whether ***living*** or ***deceased;***	(c) ***'***donor***'*** means ***a person who donates one or several*** organs, ***irrespective of*** whether ***the donation occurs during that person's lifetime*** or ***after death;***

Justification

It is fundamental to clarify that what is essential is the moment of the donation and not whether at the moment of recovery the donor passed away or not. A living donor might die after organ donation but this does not make him a deceased donor

Amendment 21

Proposal for a directive
Article 3 – point d

Text proposed by the Commission	*Amendment*
(d) 'donation' means ***donating*** human organs for ***transplantation***;	(d) 'donation' means ***the provision of*** human organs ***intended*** for ***human applications*** ;

Justification

The proposed wording defines the term 'donation' without repetition.

Amendment 22

Proposal for a directive
Article 3 – point e

Text proposed by the Commission	*Amendment*
(e) ″donor characterisation″ means the collection of the relevant information on the characteristics of the donor needed to undertake a proper risk assessment ***in order to*** minimise the risks for the recipient and to ***optimise*** organ allocation***;***	(e) ‘donor characterisation’ means the collection of the relevant information on the characteristics of the donor needed to ***evaluate his or her suitability, to*** undertake a proper risk assessment ***and*** minimise the risks for the recipient***,*** and to ***ensure effective*** organ allocation;

Justification

This new wording better reflects the purposes of the donor characterization.

Amendment 23

Proposal for a directive
Article 3 – point f

Text proposed by the Commission	*Amendment*
(f) ″European organ exchange organisation″ means a non-profit organisation, whether public or private, dedicated ***especially*** to cross-border organ exchange; the countries members of such an organisation are in their majority Member States of the Community;	(f) ‘European organ exchange organisation’ means a non-profit organisation, whether public or private, dedicated to ***national or*** cross-border organ exchange; the countries members of such an organisation are in their majority Member States of the Community;

Justification

All European Organ Exchange Organisations manage exchanges of organs within the territory of their MS and between countries.

Amendment 24

Proposal for a directive
Article 3 – point g

Text proposed by the Commission	*Amendment*
(g) ‘organ’ means a differentiated and vital	(g) ‘organ’ means ***both*** a differentiated and

part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy;	vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy***; a part of an organ is also considered to fall within the scope of this definition if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation***;

Amendment 25

Proposal for a directive
Article 3 – point h

Text proposed by the Commission	*Amendment*
(h) ***"***organ characterisation***"*** means the collection of the relevant information on the characteristics of the organ needed to undertake a proper risk assessment ***in order to*** minimise the risks for the recipient and to ***optimise*** organ allocation;	(h) ***'***organ characterisation***'*** means the collection of the relevant information on the characteristics of the organ needed to ***evaluate its suitability, to*** undertake a proper risk assessment ***and*** minimise the risks for the recipient***,*** and to ***ensure effective*** organ allocation;

Justification

This new wording better reflects the purposes of the organ characterization

Amendment 26

Proposal for a directive
Article 3 – point i

Text proposed by the Commission	*Amendment*
(i) 'procurement' means a process by which the donated organs become available;	(i) 'procurement' means a ***coordinated*** process by which the donated organs become available;

Justification

The process of procurement must be appropriately coordinated.

Amendment 27

Proposal for a directive
Article 3 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia)'making available' means the preparation, manipulation, preservation, packaging and transport of human organs;

Justification

While the Tissues Directive 2004/23/EG defines the terms 'procurement', 'processing' and 'preservation', the proposal for a Directive under review only defines the terms 'procurement' and 'preservation'. This means that essential intermediary stages such as preparation, manipulation, packaging and transport of human organs are not defined and are therefore left unregulated.

Amendment 28

Proposal for a directive
Article 3 –point j

Text proposed by the Commission	*Amendment*
(j) 'procurement organisation' means ***a health care establishment, a team or a unit of a hospital or another body which is authorised by the competent authority to undertakes procurement of*** human organs;	(j) 'procurement organisation' means ***a public or private non-profit making body, organisation or institution engaged particularly in the coordinated process of procuring and making available*** human organs;

Justification

In defining the regulatory content of the Directive, it is essential to take into account the principle of subsidiarity in accordance with Article 168(7) TFEU (formerly Article 152(5) TEC). Admittedly, recital (19) partly does so. The definitions of Article 3 of the proposal for a Directive must be brought into line with this approach. Other provisions, for instance Article 18, will have to be changed accordingly.

Amendment 29

Proposal for a directive
Article 3 – point k

Text proposed by the Commission	*Amendment*
(k) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means ***during processing*** to prevent or retard biological or physical deterioration ***of human organs*** from the procurement until the transplantation;	(k) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means***, while making available*** human organs***,*** to prevent or retard ***the*** biological or physical deterioration ***thereof*** from the procurement until the transplantation;

Justification

This amendment brings the text into line with the added definition of 'making available' (see Amendment to Article 3(i)).

Amendment 30

Proposal for a directive
Article 3 – point m

Text proposed by the Commission	*Amendment*
(m) 'serious adverse event' means any unexpected occurrence associated with ***any stage of the chain from donation to transplantation*** that might lead to the transmission of ***a communicable*** disease, to death or life-threatening***,*** disabling, ***or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;***	(m) 'serious adverse event' means any ***undesired and*** unexpected occurrence associated with ***the procurement, preservation or making available of organs*** that might lead to the transmission of ***an infectious*** disease, to death or ***a*** life-threatening ***condition or to the*** disabling ***of donors or recipients, or that might necessitate hospitalisation or cause another illness, providing it is not a matter of the side-effects of immune suppression;***

Justification

The definition of serious adverse unexpected event is so broad that it would inevitably lead to a large number of reports having nothing to do with quality or safety standards being filed. It should therefore be made slightly more restrictive, as proposed above.

Amendment 31

Proposal for a directive
Article 3 – point n

Text proposed by the Commission	*Amendment*
(n) 'serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with ***any stage of the chain from*** donation ***to*** transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in***, or prolongs,*** hospitalisation or morbidity;	(n) 'serious adverse reaction' means an unintended ***or unexpected serious*** response, including a communicable disease, in the donor or in the recipient associated with ***the*** donation***, procurement, preservation, making available or*** transplantation ***of an organ,*** that is fatal, life-threatening, disabling, incapacitating, or which results in hospitalisation or ***unexpected*** morbidity***. Side-effects of immune suppression are excluded from this definition***;

Justification

The definition of serous adverse reaction is so broad that it would inevitably lead to a large number of reports having nothing to do with quality or safety standards being filed. It should therefore be made slightly more restrictive, as proposed above.

Amendment 32

Proposal for a directive
Article 3 – point p

Text proposed by the Commission	*Amendment*
(p) 'transplantation' means the process of restoring certain functions of the human body by transferring ***equivalent*** organs to a recipient;	(p) 'transplantation' means the process of restoring certain functions of the human body by transferring ***human*** organs to a recipient;

Justification

Clarification of the meaning of 'transplantation'.

Amendment 33

Proposal for a directive
Chapter II - title

Text proposed by the Commission	*Amendment*
THE QUALITY AND SAFETY OF	***Framework for the quality and safety of***

ORGANS	***organs***

Amendment 34

Proposal for a directive
Article 4 - title

Text proposed by the Commission	*Amendment*
National quality programmes	***Framework for*** national quality ***and safety*** programmes *(This amendment applies throughout the text).*

Amendment 35

Proposal for a directive
Article 4 - paragraph 2 - point - a (new)

Text proposed by the Commission	*Amendment*
	(-a) standard operating procedures for the identification and referral of potential donors;

Justification

Identification of potential donors in the intensive care units and their referral is the indispensable prerequisite for all organ donation activities. Numerous studies show that there is a potential between 40 to 50 donors per million population in every member state. This means that every member state can increase its organ donation rate by installing a systematic analysis of the existing donor potential in all donor hospital followed by measurement in order to ensure that the donor potential is exhausted.

Amendment 36

Proposal for a directive
Article 4 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) standard operating procedures for the verification of the details of donor or donor family consent or ***authorisation*** in accordance with national rules;	(b) standard operating procedures for the verification of the details of ***the consent, or absence of any objection, of the*** donor or donor family in accordance with national rules;

Justification

This amendment takes into account the 'opting-out' character of consent which applies in most Member States.

Amendment 37

Proposal for a directive
Article 4 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) ***rules*** for the transportation of human organs in accordance with Article 8.	(e) ***procedures*** for the transportation of human organs in accordance with Article 8.

Justification

This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework. Further specifications on the different elements are provided in corresponding articles

Amendment 38

Proposal for a directive
Article 4 – paragraph 2 – points e a – e d (new)

Text proposed by the Commission	*Amendment*
	(ea) procedures to ensure traceability, guaranteeing compliance with the legal requirements on the protection of personal data and confidentiality. Such procedures shall include the responsibilities of procurement organisations and transplantation centres with regard to traceability;
	(eb) procedures for the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1), including the responsibilities of procurement organisations and transplantation centres with regard to such reporting;
	(ec) procedures for the management of serious adverse events and reactions as

	referred to in Article 11(2), including the responsibilities of procurement organisations and transplantation centres with regard to such management;
	(ed) standard operating procedures for tracing and limiting the risks of unethical or illegal activities, particularly concerning decisions for organ procurement and transplantation.

Justification

This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework. Further specifications on the different elements are provided in corresponding articles.

Amendment 39

Proposal for a directive
Article 4 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. ***The national*** quality ***programmes*** shall	3. ***The framework for the*** quality ***and safety of organs*** shall ***ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified and competent, and shall develop specific training programmes for such personnel, and shall establish standard operating procedures for:***

Justification

This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework: (a) and (b) have been moved (reworded) to paragraph 2. "Healthcare" has been included in order to leave out drivers, pilots etc. involved in the process. Including the word "competencies" better captures national realities. This should be taken into consideration for the entire text of the Directive. General agreement on adding "such", as it refers to healthcare personnel It is very difficult to recognize international standards in most of the cases

Amendment 40

Proposal for a directive
Article 4 - paragraph 3 - point b - indent 2

Text proposed by the Commission	*Amendment*
– the ***recall of organs*** as referred in Article 11(2),	– the ***management of serious adverse events and reactions*** as referred in Article 11(2),

Justification

The measures to adopt for a severe adverse event or reaction do not include necessarily the recall of organs, as defined in this directive. Occasionally, the events or the reactions appear when the organ has already been transplanted and, in that case, the transplantectomy for the recall of the organ may not be the most appropriate measure to adopt. Besides, the management of a particular safety problem would also include the revision and assessment of the procedures and results, in order to introduce corrective or preventive measures.

Amendment 41

Proposal for a directive
Article 4 - paragraph 3 - point b - indent 3

Text proposed by the Commission	*Amendment*
– the responsibilities of procurement organisations and transplantation centres in the process of reporting.	– the responsibilities of procurement organisations and transplantation centres in the process of reporting ***and management***.

Justification

When a serious adverse event or reaction appears it is mandatory to adopt a series of measures targeted to prevent. These measures do not necessarily include the recall of the organ, as defined in this Directive. Sometimes serious adverse events and reactions appear when the organ has been already grafted and transplantectomy (recall of the organ) might not be the most adequate measure to be adopted.

Amendment 42

Proposal for a directive
Article 4 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) authorise, in life-threatening emergencies, transplant operations using an organ which is not optimal, after

	consultation between the healthcare personnel and the patient, or the patient's family where the patient is unable to state his or her choice.

Amendment 43

Proposal for a directive
Article 4 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) establish the qualifications required ***by*** the personnel involved at all stages of the chain from donation to transplantation or disposal, and develop specific training programmes for personnel ***in accordance with recognised international standards***.	(c) establish the qualifications ***and competencies*** required ***for*** the ***healthcare*** personnel involved at all stages of the chain from donation to transplantation or disposal, and develop specific training programmes for ***such*** personnel.

Justification

Including the word "competencies" better captures national realities.

Amendment 44

Proposal for a directive
Article 4 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) determine the status of transplant coordinators from the stage of organ donation to that of monitoring of the recipient.

Justification

In Paragraph 12 of its resolution of 22 April 2008, the European Parliament stressed the central role played by transplant coordinators with a view to actively identifying potential donors. It is therefore essential that the national quality programmes referred to in Article 4(3) should provide for the establishment of a status of transplant coordinator.

Amendment 45

Proposal for a directive
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that the procurement takes place in ***procurement organisations*** that comply with the rules laid down in this Directive.	1. Member States shall ensure that the procurement ***and making available of organs*** takes place in ***public or private non-profit making bodies, organisations or institutions*** that comply with the rules laid down in this Directive.

Justification

This amendment brings the text into line with the definition of authorities and the making available of organs.

Amendment 46

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The organisational structure and operational procedures of procurement organisations shall include:	***deleted***
(a) an organisational chart which clearly defines job descriptions, accountability and reporting relationships;	
(b) standard operating procedures as specified in national quality programmes.	

Justification

These excessively precise details should not be included in the body of the directive.

Amendment 47

Proposal for a directive
Article 6 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that medical	1. Member States shall ensure that medical

activities in procurement organisations, such as donor selection, are performed under the advice and the supervision of a medical doctor as defined in Directive 2005/36/EC.	activities in procurement organisations, such as donor selection ***and evaluation***, are performed under the advice and the supervision of a medical doctor as defined in Directive 2005/36/EC.

Amendment 48

Proposal for a directive
Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that ***procurement*** takes place in ***dedicated*** facilities, which are designed, constructed, maintained and operated so as to comply with the requirements laid down in this Directive and which allow minimising bacterial or other contamination of procured human organs in accordance with best medical practices.	2. Member States shall ensure that ***donation*** takes place in ***appropriate*** facilities, which are designed, constructed, maintained and operated so as to comply with the requirements laid down in this Directive and which allow minimising bacterial or other contamination of procured human organs in accordance with best medical practices. ***The facilities shall meet operating theatre standards.***

Justification

Clarification.

Amendment 49

Proposal for a directive
Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Those facilities shall comply with normal standard for operating theatres, including:	***deleted***
(a) Restricted access;	
(b) personnel that are appropriately dressed for sterile operations, wearing sterile gloves, hats and facemasks.	

Justification

Such details should not be included in a European directive.

Amendment 50

Proposal for a directive
Article 8 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the organisation***s, bodies or companies*** involved in the transportation of organs ***have appropriate standard operating procedures in place to ensure the integrity of*** the organ ***during transport and that transport time is minimised***.	(a) the organisation involved in the transportation of organs ***ensures that*** the organ ***is transported with due care***;

Justification

This amendment seeks to cut red tape. What is essential is that the organ should be treated according to the rules during transport.

Amendment 51

Proposal for a directive
Article 8 – paragraph 1 – point b – indent 1

Text proposed by the Commission	*Amendment*
– identification of the procurement organisation, including its address and telephone number;	– identification of the procurement organisation ***and the donor's hospital***, including its address and telephone number;

Justification

The proposed amendment takes due account of the quality and safety requirements and addresses the specific requirements relating to organ transplantation.

Amendment 52

Proposal for a directive
Article 8 - paragraph 1 - point b - indent 4

Text proposed by the Commission	*Amendment*
– recommended transport conditions, including instructions for keeping the container at ***a certain*** temperature and in ***a certain*** position;	– recommended transport conditions, including instructions for keeping the container at ***an appropriate*** temperature and in ***an appropriate*** position;

Amendment 53

Proposal for a directive
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Competent authority shall indicate in the accreditation, designation, authorisation or licence which ***activities*** the transplantation centre concerned may undertake.	2. The Competent authority shall indicate in the accreditation, designation, authorisation or licence which ***programmes*** the transplantation centre concerned may undertake.

Justification

This amendment is intended to reflect the variety which exists among transplantation centres, as some perform all types of transplantation while others are approved only for certain transplantation programmes, for example for kidney transplants but not heart transplants.

Amendment 54

Proposal for a directive
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure the implementation of a donor identification system that can identify each donation and each of the organs associated with it. Member States shall ensure that ***this donor identification system are designed and selected in accordance with the aim of collecting, processing or using no personal data or as little personal data as***	2. Member States shall ensure the implementation of a donor identification system that can identify each donation and each of the organs associated with it. Member States shall ensure that the ***confidentiality of patient data is respected in accordance with national rules***.

possible. In particular, use is to be made of the possibilities for pseudonymisation or rendering individuals anonymous.

Justification

Too detailed since the reference to the data protection directive has been already established.

Amendment 55

Proposal for a directive
Article 10 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) access to systems permitting the identification of a donor or recipient is as restricted as possible.

Justification

With fewer people having access to data the risks of unlawful access of such sensitive data is reduced.

Amendment 56

Proposal for a directive
Article 10 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States shall, in accordance with Article 24, lay down rules on penalties applicable to:
	(a) any unauthorised accessing of data or systems that makes identification of donors or recipients possible;
	(b) any use which is made of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for necessary medical purposes.

Justification

Penalties are needed to deter people from attempting to use the systems for unauthorized

searches.

Amendment 57

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the ***procurement,*** testing, and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.	1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the testing, ***characterisation, procurement, preservation*** and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

Justification

Characterisation is also included under the scope - Article 2(1). Procurement should move after testing in order to follow the clinical process.

Amendment 58

Proposal for a directive
Article 12 a (new)

Text proposed by the Commission	*Amendment*
	Article 12a
	Third Parties
	1. Procurement organisations and transplantation centres may conclude written agreements with third parties for the carrying out of their functions.
	2. Where procurement organisations and transplantation centres enter into written agreements as referred to in paragraph 1, they shall:

	(a) evaluate and select third parties on the basis of their ability to meet the standards laid down in this Directive;
	(b) keep a complete list of the agreements referred to in paragraph 1 that they have concluded with third parties;
	(c) specify the responsibilities of the third parties and detailed procedures;
	(d) provide copies of agreements with third parties at the request of the Competent Authority.

((These arrangements were foreseen in the Tissues and Cells Directive, see Article 24 of Directive 2004/23/EC.))

Justification

There are likely to be activities which procurement organisations or transplant centres need to carry out that they would like to be carried out by third parties either now or in the future, for example the running of IT systems. This Article would ensure that these third parties comply with the quality and safety standards set out in this Directive.

Amendment 59

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that donations of human organs from deceased and living donors are voluntary and unpaid.	1. Member States shall ensure that donations of human organs from deceased and living donors are ***altruistic,*** voluntary and unpaid.

Justification

Organ donation is a gift based on solidarity and compassion for a fellow human being. Not to require an organ donation to be altruistic means to belittle the gift and the dignity of the deceased or living donor. The European Parliament acknowledged this specific requirement already in its resolution of 22 April 2008 (Resolution on organ donation and transplantation (A6-0090/2008), § 22) and the Commission took it up in § 23 of its Explanatory Memorandum.

Amendment 60

Proposal for a directive
Article 13– paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and inconveniences related to the donation.
	For such cases, Member State shall define the conditions under which compensation may be granted, while avoiding any financial incentives or benefit for a potential donor.

Amendment 61

Proposal for a directive
Article 13 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Commission, in close cooperation with Member States, the European Parliament and relevant stakeholders, shall examine the possibility of developing a system whereby the wishes expressed by citizens consenting to the donation of organs after they are deceased are taken into account in as many Member States as possible.

Justification

As people live, travel and work in several countries of the European Union, they also die in other countries than the one of which they are citizens or residents.

Amendment 62

Proposal for a directive
Article 13 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Member States shall ensure that systems and registers are in place which are easily accessible for the purposes of recording the wishes of future donors,

and that the competent authorities give priority to the wishes expressed by a donor over any possible contrary wishes of a spouse, first-degree relative or other person.

Justification

Member States should be urged to ensure that there are systems in place to communicate a wish to become a donor and that this expressed wish should be respected as a priority.

Amendment 63

Proposal for a directive
Article 13 – paragraph 3 c (new)

Text proposed by the Commission	*Amendment*
	3c. Member States shall ensure that organs are allocated to recipients according to transparent, non-discriminatory and scientific criteria.

Justification

This rule regarding the allocation of organs is the direct result of the application of the principles of equality and of justice in healthcare resource allocation.

Amendment 64

Proposal for a directive
Article 13 – paragraph 3 d (new)

Text proposed by the Commission	*Amendment*
	3d. Member States shall ensure that organs are not removed from a deceased person unless that person has been certified dead in accordance with national law.

Justification

Demanding a death certificate regarding a deceased donor before allowing the organ removal is a requirement deriving from the principle of inviolability of human life and physical integrity as laid down in Article 16 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin.

Amendment 65

Proposal for a directive
Article 13 – paragraph 3 e (new)

Text proposed by the Commission	*Amendment*
	3e. Member States shall intensify their cooperation within Interpol and Europol in order to address the problem of trafficking in organs more effectively.

Amendment 66

Proposal for a directive
Article 13 – paragraph 3 f (new)

Text proposed by the Commission	*Amendment*
	3f. Member States shall, in order to minimise the risk of organ trafficking in the Union, reduce demand, promote organ donation more effectively, maintain strict legislation with regard to live unrelated donors, guarantee transparency of national registers and waiting lists, establish the legal responsibility of the medical professional for tracking irregularities, and share information.

Amendment 67

Proposal for a directive
Article 14

Text proposed by the Commission	*Amendment*
Procurement shall only be carried out only after compliance with all mandatory consent ***or authorisation*** requirements in force in the Member State concerned.	Procurement shall only be carried out only after compliance with all mandatory consent requirements ***and all requirements relating to the absence of any objection to organ donation*** in force in the Member State concerned.

Justification

See the amendment to Article 4(2) concerning national quality programmes.

Amendment 68

Proposal for a directive
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In order to meet the quality and safety requirements laid down in this Directive, Member States shall endeavour to obtain all necessary information from living donors and to provide them with the information they need to understand the consequences of donation. In the case of deceased donation, Member States shall endeavour to obtain such information from relatives or other persons authorising donation. Member States shall make all parties, from whom information is requested, aware of the importance of swiftly transmitting such information.

Justification

Agree on the concept of the need of providing information to donors (or relatives) on the process of donation and transplantation. However, in order to keep this concept under the competencies of the EU conferred by article 168 of the TFEU, it is suggested to focus on the risks for recipients as a result of the quality and safety of the organs. As this is implicitly linked to obtaining a complete, objective and reliable clinical history by the medical team, it is also suggested to include this provision under article 7, related to the characterisation of donors and organs. We are still working on the final wording and studying the most appropriate place to locate this provision in this Directive

Amendment 69

Proposal for a directive
Article 15 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Living donation should be seen as complementary to post-mortem donation and may be carried out where there is no suitable organ available from a deceased person.

	Living donations are predominantly carried out among family members and close relatives **and/*or*** **for** ***the benefit of a recipient with whom the donor has a close personal relationship, or where it can be proven that the donor is not acting for the purpose of financial gain in order to prevent commercialisation. Particularly, in the absence of such a close relationship, adequate provisions in national law of the Member States shall be made, thus assuring the highest possible protection of living donors.***

Amendment 70

Proposal for a directive
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified and trained professionals. Such assessments may provide for the exclusion of persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or a serious risk to themselves.	2. Member States shall ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified and trained professionals. Such assessments may provide for the exclusion of persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or a serious risk to themselves. ***Member States shall also ensure that living donors are legally insured.***

Justification

Legal insurance cover is important to protect living donors. In altruistically donating organs, living donors face a significant health risk which such a measure will help to mitigate.

Amendment 71

Proposal for a directive
Article 15 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States shall ensure that no

organ removal may be carried out on a person who under national law does not have the capacity to consent to it.

Justification

Persons not having the capacity to consent to a medical procedure are in an especially dire need of protection. This may concern minors, but also adult persons lacking legal capacity. While reflecting Article 14 § 1 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, this amendment leaves it to the Member States to determine under which conditions a person is or is not capable to consent to a medical procedure.

Amendment 72

Proposal for a directive
Article 15 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Member States shall ensure follow-up in relation to living donors in accordance with national provisions, in order to identify, report, and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.

Justification

See amendment 33a

Amendment 73

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with Community provisions on the protection of personal data, such as	Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ ***donation and*** transplantation activities, in conformity with Community provisions on the protection of personal

Directive 95/46/EC, and in particular Articles 8 (3), 16, 17 and 28 (2) of that Directive.	data, such as Directive 95/46/EC, and in particular Articles 8 (3), 16, 17 and 28 (2) of that Directive.

Justification

Protection of personal data also implies donors.

Amendment 74

Proposal for a directive
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States shall take the necessary measures to ensure that donors and recipients whose data are being processed under this Directive are identifiable only by persons who can demonstrate a need to know their identities.

Justification

The concepts of 'traceability' and 'identifiability' are strongly connected to each other: whenever traceability of the holders of the biological materials is possible, either in a direct or indirect way, these holders can be considered as identifiable and they should include recipients and donors.

Amendment 75

Proposal for a directive
Article 16 - paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	Member States shall take the necessary measures to ensure the confidentiality, integrity, accountability and availability of the personal data of donors and recipients.

Justification

It is of utmost importance to implement an information security policy based on strict and sound security measures at the relevant national services, especially in order to meet the confidentiality requirements for the donors and recipients set out in the proposal, as well as to

safeguard integrity, accountability and availability of these data.

Amendment 76

Proposal for a directive
Article 17

Text proposed by the Commission	*Amendment*
Article 17	***deleted***
Anonymisation of donors and recipients	
Member States shall take all necessary measures to ensure that all personal data of donors and recipients processed within the scope of this Directive are rendered anonymous so that neither donors nor recipients remain identifiable.	

Justification

Article 17 as such could be deleted, incorporating its content (in terms of confidentiality needs) in a new paragraph of Article 16 on the Protection of personal data, confidentiality and security of processing.

Amendment 77

Proposal for a directive
Article 18 – title

Text proposed by the Commission	*Amendment*
Designation and tasks of competent authorities	Designation and tasks of the competent authorities***, organisations and institutions***

Justification

The existing organisational structures for organ donation, allocation and transplantation in the Member States are closely connected to the organisation of the national health care system in general. Recital 19 states that within Members States, a combination of local, regional, national and/or international bodies may work together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency. See also Amendment 38.

Amendment 78

Proposal for a directive
Article 18 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
The competent authorities shall, in particular, take the following measures:	The competent authorities ***or institutions*** shall, in particular, take the following measures:

Amendment 79

Proposal for a directive
Article 18 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States may delegate, or may allow a Competent Authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed suitable under national provisions. Such a body may also assist a Competent Authority in carrying out its functions.

Justification

Agree with the need of introducing the concept of the possibility of delegation. This wording is more flexible. This paragraph should be placed before the measures to take (18.2)

Amendment 80

Proposal for a directive
Article 18 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) ensure that procurement organisations and transplantations centres are ***controlled*** and audited on a regular basis to ascertain compliance with the requirements of this Directive;	(b) ensure that procurement organisations and transplantations centres are ***subject to public controls*** and audited on a regular basis to ascertain compliance with the requirements of this Directive;

Justification

Owing to the sensitive and non-profit making aspect of the organ transplant procedure and the weak position of patients waiting for a transplant, provision must be made for stringent public

control procedures for each phase of the procedure.

Amendment 81

Proposal for a directive
Article 18 – paragraph 2 - point d

Text proposed by the Commission	*Amendment*
(d) put in place a reporting system and a system for ***the recall of organs*** as provided for in Article 11(1) and (2);	(d) put in place a reporting ***and management*** system and a system for ***serious adverse events and/or reactions*** as provided for in Article 11(1) and (2);

Justification

The measures to adopt for a severe adverse event or reaction do not include necessarily the recall of organs, as defined in this directive. Occasionally, the events or the reactions appear when the organ has already been transplanted and, in that case, the transplantectomy for the recall of the organ may not be the most appropriate measure to adopt. Besides, the management of a particular safety problem would also include the revision and assessment of the procedures and results, in order to introduce corrective or preventive measures.

Amendment 82

Proposal for a directive
Article 18 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) issue appropriate guidance to health care establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal;	(e) issue appropriate guidance to health care establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal ***as well as subsequent treatment and recovery after transplantation***. ***They shall ensure that special protocols are created governing procedures for operative and post-operative stages under the responsibility of the respective operating teams, specialist pathologists and specialists in other necessary fields;***

Justification

Η διαδικασία της μεταμόσχευσης δεν τελειώνει όταν ο ασθενής έχει δεχθεί ένα μόσχευμα στην εγχείρηση μεταμόσχευσης. Η μετεγχειρητική περίοδος ανάρρωσης και θεραπείας με θεραπευτικές αγωγές για την πρόληψη της απόρριψης είναι εξίσου απαραίτητη για την επιτυχία της

μεταμόσχευσης στον ασθενή. Το γεγονός αυτό δεν πρέπει να παραβλέπεται, εφόσον έχει καίρια σημασία για την επιτυχία της μεταμόσχευσης και τη βελτίωση της υγείας του ασθενούς. Το εθνικό κέντρο μεταμοσχεύσεων θα πρέπει, συνεπώς, να καθοδηγεί τις νοσοκομειακές μονάδες σε θέματα παρακολούθησης ασθενών μετά από μεταμόσχευση. Τα ειδικά πρωτόκολλα θα διευκολύνουν τη λειτουργία των μεταμοσχευτικών κέντρων και τη διαφάνεια των διαδικασιών .

Amendment 83

Proposal for a directive
Article 18 - paragraph 2 - point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) collect relevant post-transplantation outcome data in order to allow comparable assessment of quality and safety of organ transplantation, which will serve to further improve the transplantation process at European level.

Justification

Although almost all European countries have already developed a registry that collects information on all aspects of the transplantation process, comparisons between the European registries is hampered by the lack in harmonization of definitions of terms used in organ transplantation, procedures for the collection of data on transplantation activity, and techniques for the evaluation of post-transplant outcome. This amendment calls on more cooperation.

Amendment 84

Proposal for a directive
Article 18 - paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	The competent authorities of each Member State may delegate the implementation of the measures referred to in the second paragraph to recognised organisations dedicated to carrying out such measures.

Justification

This paragraph might be of help for MS using those types of organizations.

Amendment 85

Proposal for a directive
Article 19 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that the competent ***authority***:	1. Member States shall ensure that the competent ***bodies, organisations or institutions***:

Justification

This is intended as clarification, taking into account the various national models for organising health systems.

Amendment 86

Proposal for a directive
Article 19 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) establishes and maintains a register of ***procurement organisations*** and transplantation centres.	(c) establishes and maintains a register of ***healthcare establishments, teams or departments of a hospital or of another establishment authorised to procure human organs*** and transplantation centres.

Justification

This is intended as clarification, taking into account the various national models for organising the health systems.

Amendment 87

Proposal for a directive
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall, upon the request of the Commission or another Member State, provide information on the register of ***procurement organisations*** and transplantation centres.	2. Member States shall, upon the request of the Commission or another Member State, provide information on the register of ***healthcare establishments, teams or departments of a hospital or of another establishment authorised to procure human organs*** and transplantation centres.

Justification

This is intended as clarification, taking into account the various national models for organising the health systems.

Amendment 88

Proposal for a directive
Article 20 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall set up a network of the competent authorities with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.	1. The Commission shall set up a network of the competent authorities***, bodies, organisations and institutions*** with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.

Justification

This amendment follows on from the amendment to Article 19(1).

Amendment 89

Proposal for a directive
Article 21 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that all exchanges of organs from or to third countries, are authorised by the competent authority.	1. Member States shall ensure that all exchanges of organs from or to third countries, are authorised by the competent authority***, organisation or institution. The competent authority shall consult the national Data Protection Authority in respect of developing a framework for the transfer to and from third countries of data concerning the exchange of organs. The specific regime for the transfer of personal data to third countries as laid down in Articles 25 and 26 of Directive 95/46/EC shall apply.***

Justification

A specific regime for transfer of personal data to third countries is laid down in Articles 25 and 26 of Directive 95/46/EC. Article 21 or the relevant Recital 15 of the proposal could state that the competent authority will consult with the national Data Protection Authority in order to develop the necessary framework for secure, but also fast and efficient transfer of organs' data to and from the third countries.

Amendment 90

Proposal for a directive
Article 21 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Responsibility for authorising organ exchanges with third countries may be delegated by the Member States to European organ exchange organisations.

Justification

The existing, tried and tested system for organising organ transplantation, which also provides for organ exchanges with third countries, should be maintained. However, not every organ exchange with third countries should require authorisation, only organ exchanges generally with a specific third country. In individual cases, responsibility for granting such authorisation may also be transferred to a European organisation for organ exchanges.

Amendment 91

Proposal for a directive
Article 21 - paragraph 2 - point b

Text proposed by the Commission	*Amendment*
(b) meet quality and safety requirements equivalent to the ones laid down in this Directive.	(b) meet quality and safety***, as well as donor and recipient protection,*** requirements equivalent to the ones laid down in this Directive.

Justification

Protection of organ donors and organ recipients in third countries is strictly connected to the effective protection of organ donors and organ recipients within the European Union. Hence, an authorisation for the exchange of organs shall only be granted when all requirements of the new Directive are met also by the organ donation in the third country . The current wording is

ambiguous.

Amendment 92

Proposal for a directive
Article 23

Text proposed by the Commission	*Amendment*
1. Member States shall report to the Commission before …… and every three years thereafter on the activities undertaken in relation to the provisions of this Directive, and on the experience gained in implementing it.	1. Member States shall report to the Commission before..***** and every three years thereafter on the activities undertaken in relation to the provisions of this Directive, and on the experience gained in implementing it.
2. Before ……**.** and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions ,a report on the implementation of this Directive.	2. Before...****** and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions ,a report on the implementation of this Directive.
	**** 2 years after the entry into force of this Directive.***
	***** 3 years after the entry into force of this Directive.***

Amendment 93

Proposal for a directive
Article 24

Text proposed by the Commission	*Amendment*
Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ***[…]*** and shall notify it without delay of any subsequent amendments affecting them.	Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by***** and shall notify it without delay of any subsequent amendments affecting them.
	**** 2 years after the entry into force of this Directive.***

Amendment 94

Proposal for a directive
Article 25 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Detailed rules for the following measures shall be adopted in accordance with the procedure referred to in Article 26(3):	***deleted***
(a) rules for the updating and transmission of information on human organs characterisation as detailed in the Annex;	
(b) procedures for ensuring the full traceability of organs, including labelling requirements;	
(c) procedures for ensuring the reporting of serious adverse events and reactions.	

Amendment 95

Proposal for a directive
Article 25 - paragraph 2 - introductory part

Text proposed by the Commission	*Amendment*
2. ***Detailed*** rules for the uniform implementation of this Directive, and in particular for the following measures, shall be adopted in accordance with the procedure referred to in Article 26(2):	2. ***Appropriate*** rules for the uniform implementation of this Directive, and in particular for the following measures, shall be adopted in accordance with the procedure referred to in Article 26(2):

Amendment 96

Proposal for a directive
Article 25 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the establishment and ***functioning*** of the network of the competent authorities referred to in Article 20.	(b) the establishment and ***ability to function*** of the network of the competent authorities referred to in Article 20.

Justification

The additions take into account the connection between human organ and donor characterisation (1a) and the definition provided in Article 3 (m) and (n) of the proposal for a Directive (1c, 2a and b).

Amendment 97

Proposal for a directive
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26a
	Delegated acts
	In order to achieve the objectives of this Directive, the Commission shall lay down by means of delegated acts in accordance with Articles 26a, 26b and 26c:
	(a) rules for the updating and transmission of information on human organ and donor characterisation as detailed in the Annex;
	(b) procedures for ensuring the full traceability of organs, including labelling requirements;
	(c) procedures for ensuring the reporting of unexpected serious adverse events and reactions.

Justification

The additions take into account the connection between human organ and donor characterisation (1a) and the definition provided in Article 3 (m) and (n) of the proposal for a Directive (1c, 2a and b).

Amendment 98

Proposal for a directive
Article 26 - paragraph 3

Text proposed by the Commission	*Amendment*
3. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall	***deleted***

apply, having regard to the provisions of Article 8 thereof.

Amendment 99

Proposal for a directive
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26a
	Exercise of the delegation
	1. The powers to adopt the delegated acts referred to in Article 25a shall be conferred on the Commission until...*. The Commission shall make a report in respect of the delegated powers at the latest...**, accompanied, where relevant, by a legislative proposal to extend the duration of the delegation of powers.
	2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
	3. The power to adopt delegated acts shall be conferred on the Commission subject to the conditions laid down in Articles 26b and 26c.
	**** OJ; please insert the date 3 years after the entry into force of this Directive.***
	***** OJ; please insert the date 30 months after the entry into force of this Directive.***

Amendment 100

Proposal for a directive
Article 26 b (new)

Text proposed by the Commission	*Amendment*
	Article 26b
	Revocation of the delegation
	1. The delegation of power referred to in Article 25a may be revoked by the European Parliament or by the Council.
	2. The institution which has commenced an internal procedure for deciding

	whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission stating the delegated powers which could be subject to revocation.
	3. The decision of revocation shall state the reasons for the revocation and shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Amendment 101

Proposal for a directive
Article 26 c (new)

Text proposed by the Commission	*Amendment*
	Article 26c
	Objections to delegated acts
	1. The European Parliament and the Council may object to the delegated act within a period of two months from the date of notification. At the initiative of the European Parliament or the Council this period shall be extended by two months.
	2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, the delegated act shall be published in the Official Journal of the European Union and shall enter into force on the date stated therein.
	3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Amendment 102

Proposal for a directive
Article 27 - paragraph 1 - subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ***[...]***at the latest. They shall forthwith communicate to the Commission the text of those provisions ***and a correlation table between those provisions and this Directive.***	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ...***** at the latest. They shall forthwith communicate to the Commission the text of those provisions. **** 2 years after the entry into force of this Directive.***

Amendment 103

Proposal for a directive
Article 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a This Directive shall not prevent a Member State from maintaining or introducing more stringent protective measures, provided that they comply with the provisions of the Treaty.

Justification

More stringent measures can be applied if Member States wish. This is consistent with the Tissues and Cells Directive.

Amendment 104

Proposal for a directive
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall communicate to the Commission the text of the ***main*** provisions of national law which they adopt in the field covered by this Directive.	2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Justification

The Member States should communicate all provisions of national law in the field covered by the directive.

Amendment 105

Proposal for a directive
Annex – Introduction

Text proposed by the Commission	*Amendment*
For the purpose of Article 7 the following information shall be gathered by the procurement organisation or procurement team on the characteristics of the organ and of the donor, ***following testing where necessary*** and processed in line with the legal requirements on the protection of personal data and confidentiality:	For the purpose of Article 7 the following information shall be gathered by the procurement organisation or procurement team on the characteristics of the organ and of the donor, ***bearing in mind the individual circumstances,*** and processed in line with the legal requirements on the protection of personal data and confidentiality***. In the absence of data, a decision shall be taken about the transplant after individual risk assessment of the donor and the recipient***:

Justification

The addition makes allowances for the fact that all the information and data provided for in the Annex or organ and donor characterisation are not always available or obtainable. This must not rule out transplants in individual cases. Without this addition, the number of donor organs would fall still further.